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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,437	06/25/2001	Yoko Aida	P20825	3769

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EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,437

Applicant(s)

AIDA ET AL.

Examiner

Jeffrey Stucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12-15, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7, 12, 13, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 6, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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This Office Action is in response to the amendment filed 4 May 2005. Claims 1-7, 12-15, 20, and 21 are pending. Claims 5, 7, 12, 13, 20, and 21 are withdrawn from consideration. Claims 1 and 2 are rejected and claims 3-4, 6, 14, and 15 are objected to.

Applicant again requests rejoinder of non-elected claims despite the requirement having been made final in the previous Office Action. Applicant is again reminded of the guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b), as previously set forth in the Restriction requirement.

This application contains claims drawn to an invention nonelected with traverse in the Election filed 23 September 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

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The objection to the specification and claims for failing to adhere to the requirements of the sequence rules is withdrawn in view of the amendment.

The new title of the invention is acceptable.

The rejection of claims 1-4, 14, and 15 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment to the claims.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that changes can be made to the protein while maintaining the apoptosis inducing activity.

The dependant claim 2 does not further limit independent claim 1 because there is a particular structure required in claim 1, Vpr truncated 15 amino acids from the C terminal and no indication of other changes required, whereas claim 2 allows for

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a much larger truncation as well as other changes or deletions that are not encompassed by a Vpr truncated 15 amino acids. Therefore, it is not clear what the metes and bounds of the claims are.

The rejection of claims 8-11 and 16-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the cancellation of these claims.

The rejection of claims 1-4, 6, 8-11, and 14-19 under 35 U.S.C. § 102(b) as being anticipated by Stewart et al. is withdrawn in view of applicant's arguments. The prior art does not teach an HIV-1 Vpr protein wherein 15 amino acids truncated from the C terminus.

The following is a new rejection necessitated by applicant's amendment:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are vague and indefinite because of the language "an isolated protein as being Vpr protein" which is not clear. Amending the claims to "an isolated Vpr protein" would clarify the language.

The following are new rejections:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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The claims encompass a genus of peptide sequences which comprises a sequences having unspecified changes where amino acids are "substituted, inserted, and/or deleted".

(MPEP 2163) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405

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(Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998).

The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP § 2163 - § 2163.04.

The specification provides no guidance as to which amino acids may be changed while peptide activity is retained. The change of even a single amino acid can have a profound effect on the activity of a protein, see Riffkin et al. *Gene* (1955). The fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable e.g., see Ngo et al, 1994. It is apparent that on the basis of Applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of peptide sequences as claimed; what is required is the

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knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of peptide sequences that must exhibit the disclosed biological functions as contemplated by the claims.

The mere contemplation of the claimed genus in the specification is not sufficient to support the present claimed invention directed to a genus of a peptide sequences comprises. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of peptide sequences that must possess the biological properties as contemplated by applicant's disclosure without describing what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a

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person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a peptide sequence which comprises a peptide sequence having unspecified changes where amino acids are "substituted, inserted, and/or deleted" that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the myriad of nucleic acids that fall within the scope of the claims. The specification does not provide sufficient guidance and direction as to the nature and identification of these amino acid sequences having unspecified changes where amino acids are "substituted, inserted, and/or deleted". Since it has been well known in the art at the time the invention was made that the

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amino acid sequence of a protein determines the structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of, and guidance with regard to, which amino acids in the protein's sequence are tolerant of modifications and which are conserved (i.e. expectedly intolerant to modifications). Detailed knowledge of the ways in which the protein structure relates to the function is also necessary. Therefore, it would be unpredictable which peptide sequence would provide the critical structural and functional properties, as it relates to the claim. It would require undue experimentation to produce all possible amino acid sequences without more explicit guidance from the disclosure.

There is insufficient information or guidance as to the structural and functional constraints on an amino acid sequence having unspecified changes where amino acids are "substituted, inserted, and/or deleted". Minor structural differences among structurally related compounds and compositions could result in substantially different biological properties and activities. Reasonable correlation must exist between the scope of the claims and the scope of the enablement set forth. One of skill in the art would neither expect nor predict the appropriate function of the claimed peptides as broadly as claimed. The

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state of the art is such that it can not predict what substitution will result in significant structural or functional changes. The classic example of structural/functional differences is hemoglobin where a single amino acid substitution due to a single nucleotide change has significant consequences on the ability of the mutant hemoglobin to carry oxygen. A second example comes from a bacterial protease (Riffkin et al. *Gene*, 1995), here a change in two nucleotides of the protease sequence results in the difference between virulent and benign disease. This small difference does not only results in epitope differences but also results in changes to the thermostability, elastolytic and caseinolytic activity of the protease. There is no guidance in the specification to teach where the sequence should be substituted, and therefore, the functionality of the protein would be unpredictable. It would be undue experimentation to produce all such possible peptides without more explicit guidance from the disclosure.

Claims 3-4, 6, 14, and 15 are objected to as being dependant upon rejected claims.

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A call was made to Arnold Turk in mid May indicating allowable subject matter but was not met with a favorable reply. Applicant wished to have a written Office Action.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.


JEFFREY STUCKER
PRIMARY EXAMINER